

At a Term of the Supreme Court
held in and for the County of Albany
at the Albany County Court House,
16 Eagle Street, Albany, New York
on the 16th day of October, 2009.

PRESENT: HON. _____
Justice Presiding

STATE OF NEW YORK
SUPREME COURT COUNTY OF ALBANY

In the Matter of the Application of

KENNETH BRYNIEN, as PRESIDENT of the
NEW YORK STATE PUBLIC EMPLOYEES
FEDERATION, AFL-CIO; ROBERT MASIELLO;
GALE BAPTISTE-GRAHAM; JOAN MEYER; and
KIMBERLY MEYER,

Petitioners,

For a Judgment Pursuant to *CPLR* Article 78,

-against-

RICHARD F. DAINES, as COMMISSIONER of the
NEW YORK STATE DEPARTMENT of HEALTH;
the NEW YORK STATE DEPARTMENT of HEALTH;
the STATE HOSPITAL REVIEW AND PLANNING
COUNCIL; DAVID A. PATERSON, as GOVERNOR
of the STATE of NEW YORK; and the STATE of
NEW YORK,

Respondents.

ORDER TO SHOW CAUSE

Index No. 88-53-09

RJI No. _____

Date Filed: 10/15/09

ORAL ARGUMENT
IS REQUESTED

☒ X

Upon reading and filing the annexed Petition verified on October 15, 2009, the annexed
affidavits of Robert Masiello sworn to on October 5, 2009, Gale Baptiste-Graham sworn to on

October 2, 2009, Joan Meyer sworn to on October 2, 2009, Kimberly Meyer sworn to on October 2, 2009, Jonathan Rosen sworn to on October 15, 2009, the annexed affirmation of Ira Paul Rubtchinsky, Esq., dated October 15, 2009, and the exhibits attached to the above-referenced Petition, affidavits, affirmation and proceedings heretofore had herein,

LET THE RESPONDENTS SHOW CAUSE before this Court, at the Albany County Court House, 16 Eagle Street, Albany, 12207, on the _____ day of October, 2009, at _____ o'clock in the _____ noon, or as soon thereafter as counsel may be heard, why an Order should not be entered, pursuant to *CPLR* §§6301 *et seq.*, restraining and enjoining respondents from implementing and enforcing Title 10 *NYCRR* [HEALTH] Subpart 66-3 with respect to any health care personnel in New York State.

LET THE RESPONDENTS FURTHER SHOW CAUSE before this Court at a Special Term to be held in and for the County of Albany at the Albany County Court House, 16 Eagle Street, Albany, 12207, on the _____ day of October, 2009, at _____ o'clock in the _____ noon, or as soon thereafter as counsel may be heard, why an Order and Judgment should not be entered pursuant to *CPLR* Article 78 annulling and voiding Title 10 *NYCRR* [HEALTH] Subpart 66-3 on the grounds that respondents' promulgation of Title 10 *NYCRR* [HEALTH] Subpart 66-3 was unconstitutional and was arbitrary, capricious, irrational and contrary to law, and why such other, further and different relief as to this Court may seem just and proper, together with costs and disbursements of this proceeding, should not be granted.

ORDERED, that advance notice of petitioners' application for a Temporary Restraining Order pursuant to *CPLR* §§6301, 6311, 6313 and 7805 having been given to the State of New

York through the Office of the Attorney General, and petitioners having made no prior application for the relief sought in this proceeding, the respondents and each of them are hereby temporarily stayed and restrained from: (A) implementing or enforcing, (B) authorizing or requiring others to use or act upon or (C) acting on or otherwise taking any action against or with respect to any health care personnel in New York State, or other individuals who might otherwise be adversely affected by the application of Title 10 *NYCRR* [HEALTH] Subpart 66-3, upon the grounds that the petitioners or some of them will suffer immediate and irreparable injury, loss or damage unless the respondents and each of them are restrained and stayed before a hearing can be held, and it is further

ORDERED, that the Temporary Restraining Order issued by this Court shall remain in full force and effect until there is a signed and filed final determination by this Court on the application for a preliminary injunction, it is further

ORDERED, that personal service of conformed copies of this Order and the annexed papers shall be made by personally serving any Assistant Attorney General of the State of New York on or before October __, 2009 in the City of Albany, New York, and if so accomplished, shall be deemed good and sufficient service on all respondents, and it is further

ORDERED, that copies of all responding papers on behalf of any respondents shall be personally served or served by overnight mail on William P. Seamon, Esq., attorney for the petitioners, at his office at 1168-70 Troy-Schenectady Road, P.O. Box 12414, Albany, New York 12212-2414, on or before October __, 2009, and it is further

ORDERED, that copies of reply papers to be relied upon by the petitioners in this action shall be served personally upon an Assistant Attorney General on or before 5:00 p.m. on October __, 2009.

PLEASE TAKE NOTICE, that pursuant to *CPLR* §7804(e), respondents are directed to file with the Clerk of the Court the appropriate papers, transcripts and exhibits, if any, relevant to this matter.

DATED: October __, 2009
Albany, New York

Hon.
Justice of the Supreme Court

ENTER:

Filed October __, 2009

STATE OF NEW YORK
SUPREME COURT

COUNTY OF ALBANY

In the Matter of the Application of

KENNETH BRYNIEN, as PRESIDENT of the
NEW YORK STATE PUBLIC EMPLOYEES
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the STATE HOSPITAL REVIEW AND PLANNING
COUNCIL; DAVID A. PATERSON, as GOVERNOR
of the STATE of NEW YORK; and the STATE of
NEW YORK,

Respondents.

AFFIRMATION OF
IRA PAUL RUBTCHINSKY

Index No. 8853-09

Date Filed: 10/15/09

Ira Paul Rubtchinsky hereby affirms the following statements are true under penalties of perjury pursuant to *CPLR* Rule 2106, except as to matters he states upon information and belief and as to those matters he believes them to be true:

1. I am attorney licensed to practice law in the Courts of this State and I am of counsel to William P. Seamon, Esq., the attorney of record for the petitioners named in this proceeding.
2. I make this affirmation in support of the request for injunctive relief and the ultimate relief sought by the petitioners.

NOTIFICATION OF THE ATTORNEY GENERAL

3. Pursuant to *CPLR* §§2214(d) and 7804(c), the Attorney General will be notified regarding this application for the Order to Show Cause described below.

NO PRIOR APPLICATION FOR RELIEF

4. No prior application for the relief sought in this affirmation has been made to this or any other court.

PLEADINGS AND PAPERS

5. The petitioners' pleadings consist of this affirmation and the following:
- A. The Petition, as verified on behalf of the petitioners by Steven M. Klein, Esq. on October 15, 2009,
 - B. The affidavit of petitioner Robert Masiello sworn to on October 5, 2009,
 - C. The affidavit of petitioner Gale Baptiste-Graham sworn to on October 2, 2009,
 - D. The affidavit of petitioner Joan Meyer sworn to on October 2, 2009,
 - E. The affidavit of petitioner Kimberly Meyer sworn to on October 2, 2009,
 - F. The affidavit of Jonathan Rosen sworn to on October 15, 2009.

NATURE OF THE PROCEEDING

6. The above-entitled proceeding is being brought by the petitioners against the respondents for a relief pursuant to *CPLR* §6301 *et seq.* and *CPLR* §7801 *et seq.*

7. In the alternative, the Court is respectfully requested to convert this matter to an action for declaratory judgment pursuant to *CPLR* §§103(c) and 3001, if necessary.

THE REGULATION AT ISSUE

8. Using the emergency provisions of the *State Administrative Procedure Act* (hereinafter "*SAPA*"), respondent State Hospital Review and Planning Council (hereinafter the "Council") by a vote of its members and with the approval of the Commissioner of Health, filed with the Secretary of State Subpart 66-3 as an emergency regulation (See Petition, ¶29 and Petition, Exhibit "A").

NATURE OF THE DISPUTE

9. The Subpart mandates that personnel with patient contact at certain health care facilities under the supervision of the Commissioner of Health undergo the presently available seasonal flu vaccination and be vaccinated with the H1N1 vaccine when it becomes available.

10. The Subpart lists five provisions of the *Public Health Law (PHL)* as its statutory authority, including "*PHL 2830(2)*", a reference that appears to be a typographical error since there is no such statute. The correct statute is probably *PHL §2803(2)*.

11. The first claim in the Petition (¶¶89-98) is that the Respondents have proceeded without or in excess of their jurisdiction in that none of the cited provisions specifically states that either the Commissioner or the Council has the power to impose mandatory vaccinations as required by the Subpart, and thus adoption of Subpart 66-3 was the usurpation of a function reserved to the New York State Legislature that the Legislature has not granted to the Respondents, thereby violating the constitutional separation of powers, and that as a result the Respondents or some of them violated *CPLR §§7803(2) and (3)*.

12. The second claim in the Petition (§§99-107) is that the reasons given by Respondents Commissioner and Council for claiming the need for emergency adoption of Subpart 66-3 do not meet the standards of *SAPA* and are therefore a violation of *CPLR* §§7803(2) and (3).

13. The third claim in the Petition (§§108-112) is that by creating a regulation that affects certain health care personnel and certain health care facilities and not other health care personnel or facilities, and by failing to provide coverage to the susceptible groups as acknowledged by leading governmental and health care organizations, as well as allowing other deficiencies to exist in Subpart 66-3, all without obtaining legislative guidance and direction, the Respondents or some of them have acted in an arbitrary and capricious manner, thereby violating *CPLR* §7803(3).

14. The fourth claim in the Petition (§§113-118) is that the Job Impact Statement required by *SAPA* for implementation of Subpart 66-3 is erroneous and therefore violates *CPLR* §7803(3).

15. The fifth claim in the Petition (§§119-120) is that the efficacy and safety of the annual, seasonal and/or H1N1 vaccine is unknown and, therefore, Subpart 66-3, which mandates the immunization of petitioners and others with those vaccines, violates *CPLR* §7803(3).

16. The sixth claim in the Petition (§§121-126) is that there is no religious exception for those who seek relief from the mandate in Subpart 66-3, and there are no due process procedures or elements protecting individuals subject to the mandate of the Subpart 66-3 and,

therefore, their rights under the United States and New York Constitutions are at issue, and by creating such a situation, Respondents have violated *CPLR* §7803(3).

17. Relief is sought from the Court as listed in Paragraph 128 of the Petition.

APPLICATION FOR A TEMPORARY RESTRAINING ORDER

18. This application is for an Order to Show Cause and Temporary Restraining Order.

19. Up to October 14, 2009, there was the potential that petitioner Masiello could be disciplined or terminated from employment as soon as Friday, October 16, 2009 as a result of a directive to be vaccinated as described in his affidavit (see Masiello affidavit ¶¶8-11 and Exhibit "A" attached to that affidavit). Petitioner Masiello has since been advised that the October 16, 2009 deadline has been extended to November 30, 2009. (Petition, ¶43)

20. Despite the extension of the deadline described above in Paragraph 19 of this affirmation, Affiant is aware of no present assurance or statement that the Respondents, any of them, or any health care facility will not impose an earlier deadline than the November 30, 2009 deadline mentioned above and described in Petition Exhibit "A" on one or more of the other petitioners or other individuals who may be adversely affected and who are described in the Petition.

21. Such "other individuals" as mentioned in Paragraph 20 above may be any of the approximately 4,900 health care personnel in New York who are represented by the New York State Public Employees Federation, AFL-CIO ("PEF"). (Petition, ¶¶6, 8, 10-11, 37, 44-61, 62)

22. The potential immediate and irreparable threat to each individual named or described in the Petition as being adversely affected by Subpart 66-3 is that those individuals are being forced to undergo unwanted inoculation by injection through the skin and the deposit into the body of each such individual of a vaccine, which is an action that once done cannot be reversed. (Petition, ¶¶64-65; Masiello Affidavit, ¶¶13-14; Baptiste-Graham Affidavit, ¶9; Joan Meyer Affidavit, ¶5; Kimberly Meyer Affidavit, ¶6)

23. By way of clarification, petitioner Kimberly Meyer, who is now pregnant and due to deliver her child next April (Kimberly Meyer Affidavit, ¶4), is not related to petitioner Joan Meyer (Petition, ¶19). The predicament of Kimberly Meyer, due to her pregnancy, is more fully described at Paragraphs 5 through 7 of her affidavit, and the situation of pregnant women who are being compelled to undergo flu vaccination is more fully described in Rosen Affidavit, paragraphs 79 and 33-38.

24. Since the potential threat exists to the continued employment of PEF members, and to the unborn children of pregnant PEF members unless the respondents provide assurance that no deadline will be sought that is earlier than the November 30, 2009 deadline, there continues to be the threat of immediate and irreparable injury, loss or damage to three of the petitioners, and others, through the imposition of discipline upon them or the potential loss of employment in the next few days or weeks.

25. Subpart 66-3 affects providers of health care beyond and within the control of respondents or some of them and therefore, if immediate relief is not obtained by temporarily restraining the implementation of Subpart 66-3, individuals employed by employers who do not

answer to the respondents on hiring, discipline or termination of staff members could take action under Subpart 66-3 that could adversely affect such individuals and that could not be remedied by relief granted in this proceeding.

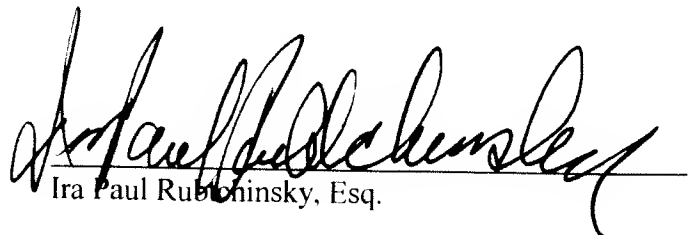
26. As a result of the potential for immediate and irreparable injury, loss or damage as describe above, this application seeks a temporary restraining order preventing implementation of the regulation until there is a determination of the application for a preliminary injunction sought in the Petition.

APPLICATION FOR AN ORDER TO SHOW CAUSE

27. Because of the November 30 deadline and the fact that a large number of PEF members as well as others may be adversely affected, the petitioners seek an Order to Show Cause with an early return date, rather than utilizing the usual notice of petition and waiting for the prescribed statutory notice period of twenty (20) days before a return date as required by CPLR §7804(c).

28. By reason of and as a result of the above, as well as by reason of and as a result of the facts stated in the Petition and the supporting affidavits and exhibits, the petitioners respectfully request an order granting a temporary restraining order, temporary injunction, permanent injunction and other relief as requested and as the Court deems just proper and equitable.

DATE: October 15, 2009


Ira Paul Rubenchinsky, Esq.

STATE OF NEW YORK
SUPREME COURT

COUNTY OF ALBANY

In the Matter of the Application of

KENNETH BRYNIEN, as PRESIDENT of the
NEW YORK STATE PUBLIC EMPLOYEES
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the STATE HOSPITAL REVIEW AND PLANNING
COUNCIL; DAVID A. PATERSON, as GOVERNOR
of the STATE of NEW YORK; and the STATE of
NEW YORK,

Respondents.

VERIFIED PETITION

Index No. 8853-09

RJI No. _____

Date Filed: 10/5/09

ORAL ARGUMENT
IS REQUESTED

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Petitioners, by their attorney, William P. Seamon, Esq. (Ira Paul Rubtchinsky, Esq. and Steven M. Klein, Esq. of Counsel), for their verified petition, respectfully allege as follows:

NATURE OF PROCEEDING

1. This petition seeks relief pursuant to *Civil Practice Law and Rules* ("CPLR") Article 78 on questions raised in *CPLR* §§7803(2) [whether the body or officer proceeded or is about to proceed without or in excess of jurisdiction] and (3) [whether a determination was made in violation of lawful procedure, was affected by an error of law or was arbitrary and capricious or an abuse of discretion].

2. The petitioners seek temporary, preliminary and permanent injunctive relief pursuant to *CPLR* Article 63, as well as other relief as directed by the Court.

3. In the event that the Court determines that this matter should properly be considered an action for declaratory judgment pursuant to *CPLR* §3001, the Court is respectfully requested to convert this action to a declaratory judgment action pursuant to *CPLR* §103(c).

JURISDICTION AND VENUE

4. This Court has jurisdiction pursuant to *CPLR* §§7800 *et seq.* and *CPLR* §3001.

5. Venue is laid in Albany County pursuant to *CPLR* §506(b) because it is the county in which the respondents maintain their main offices.

PETITIONERS

6. Petitioner Kenneth Brynien is the duly elected President of the New York State Public Employees Federation, AFL-CIO ("PEF").

7. PEF is an unincorporated association under the laws of the State of New York.

8. PEF is the duly recognized and certified collective bargaining representative for the Professional, Scientific and Technical Services ("PS&T") Unit of State employees pursuant to *Civil Service Law* §200 *et seq.* ("the *Taylor Law*").

9. PEF represents approximately 59,000 State employees, including thousands of employees who work in facilities directly under the jurisdiction of the respondent Daines and the Department of Health, and who are adversely affected by the regulation described below.

10. Upon information and belief, PEF-represented State employees who may be adversely affected by the actions described in this Petition include health care personnel at the following five facilities: State University of New York ("SUNY") Downstate Medical Center in

Brooklyn; SUNY Upstate Medical University in Syracuse; SUNY Stony Brook University Medical Center; Helen Hayes Hospital in West Haverstraw; and the Roswell Park Cancer Institute in Buffalo.

11. These health care workers include physicians, nurses, technicians and others. There may be other similarly situated individuals and other locations. Members of the PS&T Unit at facilities noted in paragraph 10 who may be affected may exceed 4,900 employees.

12. PEF has also been recognized and certified as the collective bargaining representative by the National Labor Relations Board for a bargaining unit of approximately 145 health care personnel at the Eastern Niagara Hospital-Lockport Division in Lockport, New York.

13. These PEF-represented employees work in titles including Patient Account Specialist, Patient Registration Clerk, Medical Records Clerk, X-Ray Clerk, Cashier, Phlebotomist, Senior Phlebotomist, Lab Secretary, Cardiac Services Technician, Pharmacy Technician, Dietary Technician, Respiratory Technician, Licensed Practical Nurse, Operating Room Technician, Respiratory Therapist, Radiographic Technologist, C.T. Technologist, Ultrasound Technologist, Laboratory Technologist, Nuclear Medicine Technologist, MRI Technician, Maintenance Clerk, and Certified Mammography Technician.

14. PEF is also the duly recognized and certified collective bargaining representative for a bargaining unit of Allegany County employees pursuant to the *Taylor Law*.

15. Upon information and belief, five of these PEF-represented employees were among those informed on October 5, 2009 by the Allegany County Department of Health that they are covered under the regulation challenged in this special proceeding and will be required to be vaccinated against both seasonal flu and the H1N1 flu.

16. Petitioner Robert Masiello is a PEF-represented Senior Laboratory Equipment Designer employed at the Helen Hayes Hospital. As may be seen from Mr. Masiello's attached affidavit, sworn to October 5, 2009, he has been adversely affected by the regulation described below.

17. Petitioner Gale Baptiste-Graham is a PEF-represented Registered Nurse employed at the SUNY Downstate Medical Center and licensed under the laws of the State of New York. As may be seen from Ms. Baptiste-Graham's attached affidavit, sworn to October 2, 2009, she has been adversely affected by the regulation described below.

18. Petitioner Joan Meyer is a PEF-represented Registered Nurse employed at the SUNY Downstate Medical Center and licensed under the laws of the State of New York. As may be seen from Joan Meyer's attached affidavit, sworn to October 2, 2009, she has been adversely affected by the regulation described below.

19. Petitioner Kimberly Meyer (no relation to Joan Meyer) is a PEF-represented Registered Nurse employed at the SUNY Stony Brook University Medical Center and licensed under the laws of the State of New York. As may be seen from Kimberly Meyer's attached affidavit, sworn to October 2, 2009, she has been adversely affected by the regulation described below.

RESPONDENTS

20. Respondent New York State Department of Health ("DOH") is an entity authorized under the New York State *Constitution* Article 17, §3 and created by the Legislature pursuant to the *Public Health Law* ("PHL") of the State of New York.

21. Respondent Richard F. Daines is the duly appointed Commissioner of DOH.

22. Respondent Commissioner Daines (“Commissioner”) has all of the powers and duties authorized by the Legislature of the State of New York and set forth in the statutes of the State of New York.

23. The Commissioner is being sued in that capacity.

24. DOH is the agency duly authorized to carry out responsibilities as described in the *PHL* and elsewhere.

25. Respondent David A. Paterson is the Governor of the State of New York.

26. The Governor is being sued in that capacity.

27. Respondent State of New York is a body corporate with the powers and duties set forth in the New York Constitution and applicable statutes.

28. Respondent State Hospital Review and Planning Council (“Council”) is the regulatory authority with powers and duties as authorized by *PHL* §§2803, 2900 *et seq.*, and 3612.

FACTS

29. On or about July 17, 2009, the Commissioner and DOH announced “for emergency adoption” the addition of Subpart 66-3 entitled “Health care facility personnel – influenza vaccination requirements,” to Title 10 of the *New York Codes, Rules and Regulations* (“*NYCRR*”), together with several minor conforming regulations. The regulations, the findings and the specific reasons asserted in support of the emergency rulemaking is contained in the New York State Register, and a copy of the initial emergency rulemaking as promulgated by DOH is attached as Exhibit A.

30. Upon information and belief, the Commissioner claimed that he used the emergency rulemaking procedures contained in the *State Administrative Procedure Act* ("SAPA").

31. Upon information and belief, the Council, by majority vote of its members, adopted Subpart 66-3 prior to its adoption by the Commissioner.

32. Certain health care facilities, as defined in Subpart Section 66-3.1(c), are compelled to comply with the requirements imposed upon them by the Council, the Commissioner and the Department.

33. Upon information and belief, the failure of a health care facility, as described in Subpart 66-3 (hereinafter the term "health care facility" will be utilized only with respect to those facilities that are covered under Subpart Section 66-3.1(c)), to comply with the Subpart could result in loss of licensure, loss of funds and imposition of monetary penalties among other actions that may be taken by the Council, the Commissioner or the Department.

34. Upon information and belief, use of the term "facility" in Sections 66-3.4 and 66-3.7 refers only to health care facilities as described above.

35. By the terms of Section 66-3.2, all health care facilities are required to have personnel, as that term is defined in Subpart Section 66-3.1(b), to be immunized against influenza viruses as a pre-condition of employment and on an annual basis thereafter, at no cost to the personnel, with such immunization being administered at the facility or elsewhere. (Exhibit A, Section 66-3.2 and 66-3.3)

36. Under the terms of Section 66-3.4, new personnel who enter service on or after November 30th of each year but before April 1st of each succeeding year shall have his or her status for influenza vaccination determined by the facility and, if found to be deficient, the

facility shall provide or arrange for necessary vaccinations at no cost to the new personnel or, in the alternative, such personnel may choose to receive vaccination from a source other than that arranged by the facility. (Exhibit A, Section 66-3.4)

37. The effect of Subpart 66 is to compel every health care facility to require each individual determined to be part of their "personnel" as defined in this Subpart to be vaccinated against influenza on or before November 30, 2009 and on an annual basis thereafter.

38. Upon information and belief, vaccination is to include vaccination against both the seasonal influenza and the H1N1 influenza if and when it is released. A copy of a letter of explanation from the Department dated August 26, 2009 over the signatures of Mark Kissinger, Deputy Director, Office of Long Term Care, and Richard M. Cook, Deputy Commissioner, Office of Health Systems Management, is attached as Exhibit B.

39. Upon information and belief, the mandatory vaccination will directly impact many health care personnel represented by PEF. (See, ¶¶10-15, herein.)

40. One State facility regulated by the Commissioner pursuant to *PHL* Article 28 is the Helen Hayes Hospital in West Haverstraw.

41. PEF represents approximately 250 employees at the Helen Hayes Hospital, of which approximately 210 are health care personnel covered by the emergency regulation.

42. Petitioner Masiello, a Senior Laboratory Equipment Designer employed at Helen Hayes Hospital, and all other covered health care personnel at the Helen Hayes Hospital who have not been vaccinated to date have been given a memorandum by the Hospital's administration ordering them to receive a flu shot by October 16, 2009. Employees have been further notified that their failure to comply with this directive "will be considered insubordination and will result in disciplinary action." (See, Masiello Affidavit, Exhibit A.)

43. By e-mail dated October 14, 2009, Helen Hayes Hospital has rescinded the October 16, 2009 deadline for petitioner Masiello and other personnel to comply with the vaccination mandate, and is now adhering to the November 30, 2009 deadline as set forth in Subpart 66-3. Helen Hayes Hospital continues to adhere to its position that failure to comply will be considered insubordination and will result in disciplinary action.

44. State facilities regulated by the Commissioner pursuant to *PHL* Article 28 also include the three public hospitals operated by the State University of New York ("SUNY"), which are located in Brooklyn, Stony Brook and Syracuse.

45. PEF represents approximately 685 employees at SUNY's Downstate Medical Center in Brooklyn, of which approximately 675 are covered by the emergency regulation.

46. Petitioners Baptiste-Graham and Joan Meyer are Registered Nurses employed at SUNY's Downstate Medical Center in Brooklyn.

47. These two petitioners have been notified by SUNY Downstate Medical Center that their failure to comply with the Commissioner's emergency regulation will result in discipline, up to and including termination. (See, Baptiste-Graham Affidavit, Exhibit A; Jean Meyer Affidavit, Exhibit A.)

48. SUNY Downstate Medical Center has also distributed to personnel a "Mandatory Seasonal and H1N1 Flu Vaccination: Q & A" that states, in pertinent part:

If you are not vaccinated, you will not be allowed to work or practice in a patient care environment. Failure to comply will result in penalty measures being pursued, up to and including termination from Downstate Medical Center employment. [A copy of this "Q&A" is attached as Exhibit C.]

49. PEF represents approximately 1,755 employees at SUNY's Stony Brook University Medical Center, of which approximately 1,650 are covered by the emergency regulation.

50. Petitioner Kimberly Meyer is a Registered Nurses employed at SUNY's Stony Brook University Medical Center.

51. This petitioner has been notified by SUNY Stony Brook University Medical Center that her failure to comply with the Commissioner's emergency regulation will result in discipline. (See, K. Meyer Affidavit, ¶8.)

52. PEF represents approximately 1,160 employees at SUNY's Upstate Medical University in Syracuse, of which approximately 1,155 are covered by the emergency regulation.

53. Upon information and belief, covered health care personnel at SUNY's Upstate Medical University have been advised that their failure to comply with the mandatory vaccination regulation will result in discipline.

54. Another State facility regulated by the Commissioner pursuant to *PHL* Article 28 is the Roswell Park Cancer Institute ("RPCI") in Buffalo, New York.

55. PEF represents approximately 1,200 employees at RPCI, of which approximately 1,125 are health care personnel covered by the emergency regulation.

56. In addition to these facilities, the Commissioner also regulates non-State operated public hospitals, including the Eastern Niagara Hospital in Lockport.

57. PEF represents approximately 145 employees at this facility, of which approximately 127 are health care personnel covered by the emergency regulation.

58. By memorandum dated October 8, 2009 to all employees, Eastern Niagara Hospital advised that "all personnel (with specified exceptions)" must receive both seasonal and

H1N1 influenza vaccinations by November 30, 2009. (A copy of this memorandum is attached as Exhibit D.)

59. Upon information and belief, the Commissioner's emergency regulation is also being applied to health care personnel employed by County departments of health.

60. Upon information and belief, one of these is the Allegany County Department of Health.

61. By memorandum dated October 5, 2009, five PEF-represented employees of the Allegany County Department of Health were notified that they must receive the influenza vaccinations mandated by the Commissioner's emergency regulation. (A copy of this memorandum is attached as Exhibit E.)

62. In total, PEF represents approximately 4,900 health care personnel in New York who are subject to the immediate vaccination requirement in the Commissioner's emergency regulation.

63. Upon information and belief, Exhibits C, D and E, and the affidavits of Petitioner Masiello, Baptiste-Graham, J. Meyer and K. Meyer, demonstrate that actions by the covered health care facilities have or will have an adverse impact on personnel associated with those health care facilities who are represented by PEF.

64. The action that will be taken with regard to each of the affected PEF-represented employees will be inoculation by an injection through the skin of each individual of a vaccine which will be deposited into the body of each such individual.

65. Once done, this injection cannot be reversed.

66. New York State does not mandate such vaccinations for long term care facility workers or their residents. *PHL* Article 21-A, the *Long Term Care Resident and Employee*

Immunization Act, requires facilities to offer influenza vaccinations to all employees and residents, but does not mandate that the employees and residents accept the vaccine.

67. Earlier this year, legislation (Assembly Bill A8133A/Senate Bill S3256A) was introduced in an attempt to amend this law to mandate such vaccinations, but the bill never got out of committee.

68. As may be seen from an e-mail dated September 4, 2009 from Barbara Zittel, R.N. Ph.D., Executive Secretary for the New York State Board for Nursing of the New York State Department of Education, the failure or refusal of nurses to be vaccinated as described above may result in "negative repercussions" that could be considered professional misconduct. (A copy of this e-mail is attached as Exhibit F.)

69. The Commissioner's emergency regulation is only applicable to facilities regulated pursuant to *PHL* Article 28. There are many other State health care facilities where health care personnel represented by PEF are employed.

70. For example, PEF represents Registered Nurses, Medical Doctors, and Physicians Assistants, among others, employed at State facilities operated by the Office of Mental Health, the Office of Mental Retardation and Developmental Disabilities, the Department of Correctional Services, the State Insurance Fund, the Employee Health Service operated by the Department of Civil Service, the Office of Children and Family Services, the Office of Alcoholism and Substance Abuse Services, SUNY on-campus student health clinics, and other facilities operated by the Department of Health.

71. The vast majority of the health care personnel represented by PEF at these facilities have direct patient care duties, yet none of them have been mandated by the State to receive flu vaccines.

72. Additionally, the health care personnel PEF represents at facilities that are not covered by the emergency regulation often work in very close proximity with health care personnel who are covered by the emergency regulation.

73. For example, PEF represents hundreds of health care personnel who have patient care duties at the Capital District Psychiatric Center ("CDPC") in Albany.

74. CDPC is located at 75 New Scotland Avenue in Albany, within the same city block as Albany Medical Center, which is located at 43 New Scotland Avenue and which is a facility covered by the emergency regulation.

75. It is not uncommon for patients to be transferred from CDPC to Albany Medical Center, or vice versa.

76. Due to the incomplete nature of the emergency regulation, patients coming into Albany Medical Center from CDPC may already have caught the flu at CDPC, bringing with them the very real potential to infect other patients at Albany Medical Center.

77. Similarly, patients leaving Albany Medical Center for CDPC run the risk of being exposed to both the seasonal and H1N1 flu strains once they get to CDPC. For these patients, mandatory vaccination of the health care personnel at Albany Medical Center would seem to afford them very little protection.

78. Likewise, the Samuel S. Stratton Veterans Administration Hospital in Albany, a federal facility, is located within a few hundred yards of Albany Medical Center. Health care personnel at the Veterans Administration Hospital are not mandated to receive any flu vaccinations.

79. The preceding demonstrates that of three health care facilities located within a few hundred yards of one another, only one is required to vaccinate its health care personnel.

80. Moreover, thousands of other health care personnel employed throughout New York have not been mandated by the State to receive flu vaccines.

81. The federal Centers for Disease Control ("CDC") lists five groups who should have priority in receiving the H1N1 vaccine. These groups are pregnant women; household contacts and caregivers for children younger than 6 months of age; health care and emergency personnel; all people 6 months through 24 years of age; and persons 25 through 64 who have health conditions associated with a higher risk of medical complications from influenza. The emergency regulation only arguably protects one small subset of one of these groups, health care workers.

82. For example, no school nurses or other health care personnel employed at the thousands of public or private schools in New York have been mandated by the State to receive any flu vaccine, despite the fact that the CDC has identified young children as one of the groups most at risk from influenza.

83. Additionally, none of the thousands of health care personnel employed at nursing homes in New York have been mandated by the State to receive a flu vaccine, despite the fact that CDC has identified persons 65 years of age or older as one of the groups most at risk from influenza.

84. Moreover, none of the thousands of child care workers in facilities licensed by the State are covered by this regulation, despite caring for one of the five priority groups discussed above.

85. Nor have any health care workers who work in Ob/Gyn offices or clinics, such as doctors and nurses, been mandated to receive the inoculations, despite their regular exposure to pregnant women, one of the CDC's five priority groups.

86. Private ambulance company personnel who have direct patient care responsibilities have not been mandated by the State to receive any flu vaccine, despite the fact that Emergency Medical Technicians, Critical Care Technicians, and Paramedics employed by these companies regularly transport chronically ill patients. The CDC has identified the chronically ill as one of the groups most at risk from influenza.

87. Thus, the respondent's emergency regulation fails to apply to or protect the vast majority of most at risk individuals as identified by the CDC, making it arbitrary, capricious and irrational.

88. The actions described above, upon information and belief, constitute immediate and irreparable injury, loss or damage to each PEF-represented employee required to be vaccinated.

**AS AND FOR A FIRST CLAIM, THE RESPONDENTS HAVE PROCEEDED
WITHOUT AND IN EXCESS OF THEIR JURISDICTION**

89. Petitioner repeats each and every allegation contained in the above paragraphs of this Petition.

90. Upon information and belief, the fundamental policy-making responsibility that should have been undertaken by the New York State Legislature was assumed by the respondents or certain of them, thereby violating the separation of powers doctrine.

91. Upon information and belief, one or more of the respondents stretched its or their responsibility to encompass the actions taken in Subpart 66-3 without authority.

92. New York State *Administrative Procedure Act* ("SAPA") §§ 202(6)(D)(i) and 202-a require that the notice of the emergency adoption of a rule must "cite the statutory authority, including particular sections and subdivisions, under which the rule is adopted."

93. The rule, as published in the *New York State Register*, cites as its statutory authority the following provisions of the *Public Health Law*: Sections 2166, 2800, 2830(2), 3612 and 4010(4).

94. Upon information and belief, the citation to *PHL* § 2830(2) is a typographical error and that respondents meant to cite to *PHL* § 2803(2).

95. None of the provisions of the *Public Health Law* cited above specifically states that the respondents or any of them have the authority to adopt a rule mandating that a class of healthcare workers is required to obtain the vaccination as described in the Subpart.

96. Upon information and belief, the New York State Legislature has not delegated to the respondents or any of them individually the specific responsibility of requiring healthcare facilities to mandate or require all personnel to be immunized against influenza viruses as a precondition to employment and/or on an annual basis. There is no statutory authority compelling such healthcare facilities to notify or compel all personnel to be immunized against influenza viruses as a precondition to employment and on an annual basis.

97. The promulgation of Subpart 66-3 requiring mandatory vaccinations for one group of health care workers in New York State may only be accomplished by the State Legislature in furtherance of the State's public policy.

98. Therefore, by proposing, implementing and enforcing Subpart 66-3, respondents acted in excess of their jurisdiction, violated the separation of powers doctrine, acted unconstitutionally, and such actions are arbitrary, capricious, irrational and contrary to law.

**AS AND FOR A SECOND CLAIM, THE RESPONDENTS HAVE FAILED TO
DEMONSTRATE THE REQUIRED CONDITIONS FOR ADOPTION OF
EMERGENCY REGULATION**

99. Petitioner repeats each and every allegation contained in the above paragraphs of this Petition.

100. Upon information and belief, annual, or seasonal flu happens every year.

101. Upon information and belief, H1N1 is no more virulent than seasonal flu.

102. The respondents have failed to demonstrate the required conditions for adoption of emergency regulations.

103. *SAPA* §202(6)(d)(iv) requires certain findings in order to support an emergency rule.

104. Upon information and belief, the findings provided by the respondents or any of them in connection with the Subpart fails to comply with that provision of *SAPA*.

105. Upon information and belief, respondent DOH has stated that this emergency regulation has been in development at DOH for two years. (See, Rosen Affidavit, ¶22.)

106. Upon information and belief, no emergency exists to support the utilization of the emergency regulation in *SAPA* §202(6)(d)(iv).

107. Therefore, adoption of the emergency regulation at issue herein was irrational, arbitrary, capricious and contrary to law.

**AS AND FOR A THIRD CLAIM, THE ACTION OF THE RESPONDENTS, AND
EACH OF THEM, WITH RESPECT TO THE SUBPART, IS ARBITRARY,
CAPRICIOUS AND/OR ABUSE OF DISCRETION**

108. Petitioner repeats each and every allegation contained in the above paragraphs of this Petition.

109. Upon information and belief, regardless of whether emergency conditions were to exist, utilizing rule making authority for only a segment of the healthcare population without explaining why that segment was chosen and not another segment or not all segments of the public and private healthcare community of the State of New York is arbitrary, capricious, irrational, an abuse of discretion, and demonstrates why the public policy in this instance must be left to the Legislature.

110. Upon information and belief, assuming *arguendo* that emergency conditions were to exist, utilizing rulemaking authority for only a segment of the healthcare population without explaining why that segment was chosen and not another segment or not all segments of the healthcare community including healthcare employees employed by other State agencies including the Department of Correctional Services, Office of Mental Health, Office of Mental Retardation and Developmental Disabilities, Department of Education or other State agencies, entities, and/or public authorities of the State of New York is arbitrary, capricious, irrational and an abuse of discretion.

111. By way of example, the Subpart does not cover nursing homes, while *PHL* Article 21-A does.

112. Upon information and belief, the failure to include State agencies and entities in the mandatory aspect of Subpart 66-3 creates a patchwork quilt of action demonstrating the need for Legislative attention and statutory guidance, as well as demonstrating the arbitrary, capricious and irrational conduct of the respondents and each of them in adopting the Subpart.

**AS AND FOR A FOURTH CLAIM, THE REGULATIONS' CLAIM THAT IT HAS
NO IMPACT ON JOBS IS NOT SUPPORTED BY THE FACTS**

113. Petitioner repeats each and every allegation contained in the above paragraphs of this Petition.

114. Certain Petitioners (See, Affidavits of Masiello, Baptiste-Graham, J. Meyer and K. Meyer) and thousands of other State employees (See, Exhibits C, D, and E) have been told that failure to comply with the Regulation can or will lead to discipline, up to and including termination.

115. Certain members of the PS&T Unit, such as petitioner Joan Meyer, have indicated that if they are subjected to the requirement of the Subpart, they will retire or resign from employment. (See, J. Meyer Affidavit, ¶6.)

116. Nonetheless, the regulation's Job Impact Statement erroneously states that the regulation will "not have a substantial adverse effect on jobs and employment opportunities." (Exhibit A, p. 25)

117. Moreover, upon information and belief, there is a shortage of experienced Registered Nurses in the State, and their separation from employment in facilities covered by the Subpart will create a substantial economic impact for employers and the community at large, contrary to the respondents' assertions in the regulation's Regulatory Impact Statement. (Exhibit A, p. 16)

118. Respondents' failure to include a Job Impact Statement therefore violates *SAPA* §201-a(2) and is arbitrary, capricious, irrational and contrary to law.

AS AND FOR A FIFTH CLAIM, THE RESPONDENTS' REQUIREMENT THAT SOME HEALTH CARE WORKERS TAKE AN UNTESTED OR INEFFECTIVE VACINE IS ARBITRARY, CAPRICIOUS AND/OR ABUSE OF DISCRETION

119. Petitioner repeats each and every allegation contained in the above paragraphs of this Petition.

120. Upon information and belief, the efficacy of the annual or seasonal flu vaccine and/or H1N1 vaccine is unknown due to lack of testing, especially on pregnant women and for other reasons and, consequently, the action in this regard of the respondents and each of them mandating such vaccines is arbitrary, capricious, irrational and an abuse of discretion.

AS AND FOR A SIXTH CLAIM, THE ACTIONS OF THE RESPONDENTS AND EACH OF THEM ARE CONSTITUTIONALLY DEFICIENT

121. Petitioner repeats each and every allegation contained in the above paragraphs of this Petition.

122. The Subpart contains no exception for those who do not submit to vaccinations for religious reasons and, therefore, the Subpart violates the religious freedom sections of the United States Constitution and the New York State Constitution.

123. The effect of the implementation of the Subpart may result in loss of jobs of the petitioners and other members of the PS&T Unit and, consequently, liberty and property interest of those individuals as guaranteed by the United States Constitution and the New York State Constitution has or maybe adversely effective and, consequently, this Subpart is unconstitutional.

124. The Subpart contains no elements of due process for the petitioners or other members of the PS&T Unit to obtain an exemption with respect to the Subpart and,

consequently, the due process rights of the petitioners and other members of the PS&T Unit maybe adversely affected.

125. Upon information and belief, the Subpart violates the United States Constitution and the New York Constitution.

126. Upon information and belief, no previous application for the relief sought herein has been made.

WHEREFORE CLAUSE

127. Petitioners repeat each and every allegation contained in the above paragraphs.

128. Petitioners respectfully request that an order and judgment be entered pursuant to Article 78 of the *CPLR* as follows:

- A. The Court is respectfully requested to temporarily restrain respondents from applying or enforcing Subpart 66-3 in its entirety.
- B. The Court is respectfully requested to grant an order and judgment against the Respondents and each of them that they be preliminarily and permanently enjoined from utilizing and implementing the Subpart 66-3 or encouraging, authorizing or requiring others to do so.
- C. The Court is respectfully requested to declare Subpart 66-3 invalid, null and void on the grounds that respondents and each of them have acted and continue to act in an arbitrary, capricious and irrational manner.
- D. The Court is respectfully requested to declare Subpart 66-3 invalid, null and void on the grounds that respondents and each of them proceeded and is about to proceed without and in excess of their jurisdiction in violating the New York State and United States Constitutions.

- E. The Court is respectfully requested to convert this special proceeding to declaratory judgment action if and in the event that the Court deems such action necessary and proper.
- F. The Court is respectfully requested to order a trial or hearing of facts if the Court deems such action necessary and proper in this proceeding.
- G. The Court is respectfully requested to grant such other further and different relief as it deems just, proper and equitable, together with the costs and disbursements of this proceeding.

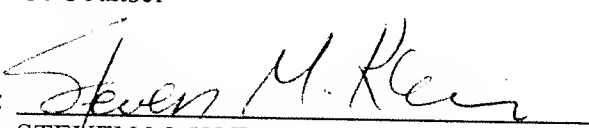
DATED: October 15, 2009
Albany, New York

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By:


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Of Counsel

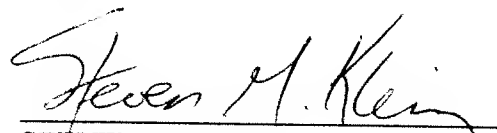
VERIFICATION

STATE OF NEW YORK)
)
COUNTY OF ALBANY) SS.:


STEVEN M. KLEIN, being duly sworn deposes and says: deponent is an attorney admitted to practice in the courts of New York State and is of counsel to William P. Seamon, Esq., attorney of record for the Petitioners in the within proceeding; deponent has read the foregoing Order to Show Cause and Verified Petition and knows the contents thereof; the same is true to deponent's own knowledge, except to matters stated to be alleged on information and belief, and as to those matters deponent believes them to be true. This verification is made by deponent and not by any petitioners because none of the petitioners are within the county where deponent has his office and because all these petitioners are united in interest in this special proceeding.

The grounds for deponent's belief as to all matters not stated upon deponent's knowledge are as follows: examination of relevant documents and discussion with petitioners or affiants.

DATED: October 15, 2009


STEVEN M. KLEIN

Sworn to and subscribed before me
this 15th day of October 2009.



Notary Public

MARIA BETOR
Notary Public, State of New York
No. 01BE6038216
Qualified in Albany County
Commission Expires March 6, 20 10

Pursuant to the authority vested in the State Hospital Review and Planning Council and the Commissioner of Health by Public Health Law Sections 2803, 3612, and 4010, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, is amended, to be effective upon filing with the Secretary of State, as follows:

Part 66 is amended to add Subpart 66-3, as follows:

Title: Subpart 66-3 – Health care facility personnel - influenza vaccination requirements

Sec.

66-3.1 Definitions

66-3.2 Health care facility – personnel influenza vaccination requirements

66-3.3 Health care facility requirements, existing personnel

66-3.4 Health care facility requirements, new personnel

66-3.5 Documentation

66-3.6 Exceptions

66-3.7 Reporting Requirements

Section 66 - 3.1 – Definitions

(a) "Medically contraindicated" means a physician licensed to practice in the State of New York or a nurse practitioner certified to practice in the State of New York certifies that influenza vaccine(s) should not be administered to an individual because it would be detrimental to the individual's health. Medical contraindication shall continue until such immunization is found no

longer to be detrimental to the individual's health. Nationally recognized up-to-date guidance for medical contraindications and recommendations for vaccination(s) for influenza will be posted on the New York State Department of Health immunization page website and will be updated regularly.

(b) "Personnel" means all persons employed or affiliated with a healthcare facility, whether paid or unpaid, including but not limited to employees, members of the medical staff, contract staff, students, and volunteers, who either have direct contact with patients or whose activities are such that if they were infected with influenza, they could potentially expose patients, or others who have direct contact with patients, to influenza; provided, however, that the provisions of this subpart shall not apply to those individuals employed or affiliated with a facility that have neither direct contact with patients nor activities that could potentially expose patients or others who have direct contact with patients. This shall include, but not be limited to, any individual whose (i) job site is physically separated from patient care locations, and who has no direct contact with patients; and (ii) job activities would result in no more than infrequent and/or incidental direct contact with others who might have direct contact with patients; provided, that such direct contact is unlikely to transmit influenza. Examples include, but are not limited to, administrative, data entry, and building or property maintenance functions that meet the criteria of items (i) and (ii).

(c) "Health Care Facilities" include general hospitals as defined in section 2801 of the Public Health Law, diagnostic and treatment centers as defined in section 751.1 of part 751 of this Title, certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs and licensed home care services agencies as

defined in section 3602 of the Public Health Law, and hospices as defined in section 4002 of the Public Health Law.

Section 66 - 3.2 – Health care facility - personnel influenza immunization requirements

Every health care facility in this state shall notify all personnel of the requirement and require that personnel be immunized against influenza virus(es) as a precondition to employment and on an annual basis. Such influenza vaccination(s) must be in accordance with the national recommendations in effect at the time of vaccination(s), unless the commissioner has determined that there is not an adequate supply of vaccine. If the commissioner determines the vaccine supplies are not adequate given the numbers of personnel to be vaccinated or vaccine(s) are not reasonably available, the commissioner may suspend the requirement(s) to vaccinate and/or change the annual deadline for such vaccination(s), as established in this subpart.

Section 66 - 3.3 – Health care facility requirements, existing personnel

Each health care facility must provide or arrange for influenza vaccination(s), at no cost to its personnel, either at the facility or elsewhere. Personnel may choose to receive influenza vaccination(s) from a source other than that arranged for by the facility and provide documentation to the facility as described in Section 66 – 3.5. Annual influenza vaccination(s) and the documentation thereof shall take place no later than November thirtieth of each year.

66 - 3.4 – Health care facility requirements, new personnel

Personnel newly entering into service at a facility after November thirtieth but before April first of each year shall have his or her status for influenza vaccination(s) determined by the facility

and, if found to be deficient, the facility shall provide or arrange for the necessary vaccination(s) at no cost to the new personnel. Instead of obtaining influenza vaccination(s) from the facility, personnel may choose to receive influenza vaccination(s) from a source other than that arranged for by the facility and provide documentation as described in Section 66 – 3.5.

Section 66 - 3.5 - Documentation

The health care facility shall document the annual vaccination(s) against influenza virus of all personnel in their personnel files, including the date, site of administration, type of vaccine, dose, manufacturer and lot number of the vaccine, reactions if any, vaccine information statement given, and the name of the person administering the vaccines. If any personnel receive influenza vaccination(s) from other than facility staff, the facility shall document in the personnel file the date, type of vaccine, dose and name of the person administering the vaccine.

Section 66 – 3.6 - Exceptions

No personnel shall be required to receive an influenza vaccine if the vaccine is medically contraindicated for that individual. Nationally recognized up-to-date guidance for medical contraindications and recommendations for vaccination(s) for influenza will be posted on the New York State Department of Health immunization page website and will be updated regularly. The facility shall, on a case-by-case basis, evaluate what steps those who are not vaccinated pursuant to this section must take to reduce the risk of transmitting influenza to patients.

Section 66 - 3.7 - Reporting Requirements

Each facility shall collect aggregate data on personnel influenza vaccination(s) status for the period beginning April first and ending March thirty-first of each year and report that data to the

department by May first of the same year in a manner determined by the commissioner. Required data will include, but not be limited to, number of personnel immunized by occupation, total number of personnel by occupation, and reason(s) personnel did not receive vaccine.

Subparagraph (v) of paragraph (10) of subdivision (b) of Section 405.3 of Part 405 is added to read as follows:

(v) documentation of preemployment and annual vaccination(s) against influenza, in accordance with Part 66 of this Title.

Paragraph (6) of subdivision (d) of Section 751.6 is added to read as follows:

(6) documentation of preemployment and annual vaccination(s) against influenza, in accordance with Part 66 of this Title.

Paragraph (5) of subdivision (c) of Section 763.13 is added to read as follows:

(5) documentation of preemployment and annual vaccination(s) against influenza, in accordance with Part 66 of this Title.

Paragraph (6) of subdivision (d) of Section 766.11 is added to read as follows:

(6) documentation of preemployment and annual vaccination(s), in accordance with Part 66 of this Title.

Paragraph (6) of subdivision (d) of Section 793.5 is added to read as follows:

(6) documentation of preemployment and annual vaccination(s) against influenza, in accordance with Part 66 of this Title.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of the regulatory changes adding Subpart 66-3 and amending Sections 405.3, 751.6, 766.11 and 793.5 of Title 10 is contained in Sections 2803 (2), 3612 and 4010 (4) of the Public Health Law (PHL). PHL section 2800 places the comprehensive responsibility for the development and administration of the state's policy with respect to Article 28 facilities with the State Department of Health. PHL Section 2803(2) authorizes the State Hospital Review and Planning Council (SHRPC) to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities. PHL Section 3612 authorizes the SHRPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, with respect to certified home health agencies, providers of long term home health care programs and providers of AIDS home care programs. PHL Section 4010 (4) authorizes the SHRPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, with respect to hospice organizations.

Legislative Objectives:

The legislative objective of PHL Article 28 includes the protection of the health of the residents of the State by assuring the efficient provision and proper utilization of health services, of the highest quality at a reasonable cost. PHL Article 36 states a public commitment to the appropriate provision and expansion of services rendered to the residents of the State by certified home health agencies, to the maintenance of a consistently high level of services by all home care services agencies, to the central collection and public accessibility of information

concerning all organized home care services, and to the adequate regulation and coordination of existing home care services. PHL Article 40 declares that hospice is a socially and financially beneficial alternative to conventional curative care for those afflicted by terminal illness. In recognition of the value of hospice and consistent with State policy to encourage the expansion of health care service options available to New York State residents, it is the intention of the Legislature that hospice be available to all who seek such care and that it become a permanent component of the State's health care system. Immunizing staff of these providers against influenza will promote the health and safety of the patients they serve and support efficient provision of services.

Needs and Benefits:

The State Department of Health strongly advocates that all health care personnel (HCP) should receive annual influenza vaccination(s). This recommendation was communicated in two letters from the Commissioner (dated October 2006 and September 2007), and a health advisory (dated December 14, 2007), sent to hospitals, long term care facilities, providers and local health departments. PHL Article 21-A, the Long Term Care Resident and Employee Immunization Act, currently requires that all long-term care facilities, adult homes, adult day healthcare facilities, and enriched housing programs offer influenza vaccine to all employees and residents. Further amendments to PHL Article 21-A have been introduced to require all HCP under its purview to receive annual influenza vaccination(s).

The intent of this regulation is to coordinate the influenza vaccination requirements for personnel in Article 28, Article 36, and Article 40 entities to be the same; however, each type of

entity has a separate set of regulations that apply to them. In order to avoid the need to revise multiple regulations in the event of future changes to Subpart 66-3, the regulations for each type of provider entity will refer to one central set of requirements in Part 66. The authority for the Part 66-3 regulation, as applying to the affected types of facilities, rests with the State Hospital Review and Planning Council.

Each year, influenza causes significant morbidity and mortality in the United States, especially among the vulnerable populations in hospitals and long term care facilities. Common symptoms include the sudden onset of headache, high fever, cough, sore throat, fatigue and body aches. Complications of influenza may include bacterial or viral pneumonia; dehydration; the worsening of chronic medical conditions, such as congestive heart failure, asthma, or diabetes; or death. The risk for complications, hospitalization, and death from influenza are higher among persons 65 years of age or older, young children, and persons with chronic medical conditions. Influenza is the sixth leading cause of death among adults in the United States, killing an average of 36,000 Americans annually and causing more deaths than all other vaccine-preventable diseases combined.

Influenza viruses spread mainly from person to person when an infected individual coughs or sneezes. Most healthy adults, including HCP, may be able to infect others beginning 1-2 days before symptoms develop and up to 5 days after becoming sick. That means HCP may be able to pass on the disease to a patient before they are aware they are sick or they may continue to work while they are contagious.

Influenza Infections in Hospitals and Long Term Care Facilities. Tables 1 and 2 detail the burden of nosocomial influenza infections (i.e., influenza infections acquired in hospitals and long term care facilities) in New York State by using NYSDOH surveillance data from 2001 to 2006. During the 2005-06 influenza season, there were 205 confirmed outbreaks in New York State hospitals and long-term care facilities. There were 1,896 suspected and confirmed cases of influenza associated with these reported outbreaks. As shown in Tables 1 and 2, the number of outbreaks and cases varies significantly year to year depending on the severity of that year's influenza season.

Table 1: Confirmed Influenza Outbreaks in New York State Hospitals and LTCFs

	2000-01	2001-02	2002-03	2003-04	2004-05	2005-06	2006-07	Total
Number of outbreaks reported to NYSDOH	31	173	24	199	451	205	70	1153

Source: NYSDOH surveillance data

Table 2: Morbidity from Nosocomial Influenza Infections in New York State

	2000-01*	2001-02	2002-03	2003-04	2004-05	2005-06	2006-07	Total
Number of patients/residents reported ill (suspected and confirmed) with nosocomial influenza in hospitals and LTCFs	359	2814	403	3535	8675	2603	663	19,052
Number of staff reported ill (suspected and confirmed) with nosocomial influenza in hospitals and LTCFs	55	889	146	1105	2124	702	158	5,179

Source: NYSDOH surveillance data

*Nosocomial data is only available from January 1, 2001 forward.

Role of HCP in Influenza Transmission. Influenza transmission and outbreaks in hospitals and nursing homes are well documented. HCP can acquire influenza from infected patients or the community and transmit influenza to patients and other staff. Many HCP develop no or only mild symptoms of the disease and, therefore, do not realize they have influenza and can transmit the disease to patients. Since influenza can be transmitted 1-2 days before the onset of symptoms, patients are at risk even if HCP do stay at home while ill.

A few studies provide estimates of the incidence of influenza-like illness among HCP. According to the CDC, "In one serosurvey of HCP, 23% had documented serologic evidence of influenza infection after a mild influenza season; however, of these, 59% could not recall having influenza, and 28% could not recall any respiratory infection, suggesting a high proportion of asymptomatic illness." In addition, multiple studies have also shown that HCP continue to work despite being ill with influenza, increasing exposure of patients and coworkers. When HCP

come in to work while ill, whether it is because they do not want to lose sick time or pay or out of a sense of obligation, influenza virus can be transmitted to patients and other staff.

Studies have shown that influenza outbreaks in health facilities are associated with low vaccination rates among HCP and that, conversely, high vaccination rates among HCP are associated with fewer outbreaks. One study looked at the yearly incidence of lab-confirmed influenza illness among both staff and patients over 12 influenza seasons in an acute care facility, from 1999-2000. As the influenza vaccine rate climbed from 4% to 67%, the proportion of influenza cases decreased among hospitalized patients from 32% to 0, and among staff from 42% to 9%.

Influenza outbreaks in long-term care facilities are common and can cause severe outcomes in the vulnerable resident populations. Older adults in nursing homes often have multiple chronic or acute conditions that make them particularly susceptible to the complications of influenza disease. The intimate and constant care that is required by residents from the HCP who care for them allows for ready transmissibility from symptomatic or asymptomatic infected staff members. In addition, because influenza vaccination(s) is/are less effective among frail and elderly patients, outbreaks can occur in facilities where a high proportion of residents or patients are immunized. High vaccination levels of HCP are needed to protect patients, making influenza vaccination(s) of HCP an important patient safety issue.

A Scottish study compared mortality rates between long-term care hospitals that offered influenza vaccination to HCP, where 51% were vaccinated, and hospitals that did not, where

only 5% were vaccinated. The result was nearly a 40% reduction in all-cause mortality among the patients cared for by HCP in the hospitals with higher levels of HCP influenza vaccination.

Yet, despite the documented and positive effects of immunizing HCP against influenza on patient outcomes, HCP absenteeism, and reducing influenza infection among staff, and incentives to promote vaccination(s) of HCP, 30–50% continues to remain unvaccinated.

In 2000, New York State enacted Public Health Law Article 21-A requiring long-term care facilities to offer influenza vaccine to all residents and HCP and to document refusal of the vaccine. As seen in NYSDOH survey data, while the overall vaccination of residents has improved to 80% or greater in most facilities, the response among HCP has been poor (less than 45%).

CDC and National Recommendations. Recognizing the need to protect hospital patients and long-term care facility residents, the Centers for Disease Control and Prevention (CDC) has recommended influenza vaccination(s) for health care personnel (HCP) since 1981.

In November 2003, 24 leading organizations endorsed a policy to make annual influenza vaccination(s) among HCP an important goal for public health and safety. These organizations included the Society for Hospital Epidemiology of America, the American Medical Association, the American Academy of Family Practitioners, the American Academy of Pediatrics, and the American Nurses Association.

In February 2006, the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP) jointly recommended that all HCP be vaccinated annually against influenza.

In January 2007, the Infectious Disease Society of America called for a mandatory requirement for all HCP to receive influenza vaccination yearly.

Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity

The cost to regulated entities to vaccinate personnel should be modest. Personnel in hospitals, diagnostic and treatment centers, home care services agencies and hospices all must undergo a health assessment to ensure that such personnel are free from a health impairment which is a potential risk to patients or which may interfere with the performance of his/her duties. Personnel are also required to have a certificate of vaccination against measles and rubella unless medically contraindicated and be tested for tuberculosis as condition of employment or affiliation. It should be noted that measles and rubella are one-time vaccinations, while influenza vaccination(s) is/are given annually. Many, if not most, facilities recognize the importance of their personnel receiving such vaccination(s) and already offer it to them, usually at no charge. Influenza vaccine is one of the least expensive vaccines and the average price in the private sector ranges from approximately \$9.75 to \$19.70 per dose.

Any additional costs to vaccinate all personnel should be more than offset by cost savings to the facility. Cost-effectiveness studies of adults aged <65 years indicate that vaccination(s) can reduce both direct medical costs and indirect costs from work absenteeism, resulting in 13%-

44% fewer health-care provider visits, 18%-45% fewer lost workdays, 18%-28% fewer days working with reduced effectiveness, and a 25% decrease in antibiotic use for influenza-like illness (ILI). HCP absenteeism can be a serious cause of staffing shortages during the influenza season at a time when emergency room visits and admissions due to influenza-related illness are greatly increased. The benefit of an immunized staff decreases direct and indirect costs to health care facilities.

Before 12/1/09, for inpatient hospital reimbursement, flu costs incurred prior to 12/1/09 may be the subject of a rate appeal per 10 NYCRR 86-1.17(a)(3). Section 86-1.17(a)(3) permits application for prospective revisions of certified rates and established revenue caps in the current year based on "[D]ocumented increases in the overall operating costs of a medical facility resulting from the implementation of additional or expanded programs, staff or services specifically mandated for the facility by the commissioner." After that time, the new hospital reimbursement system, PHL section 2807-c, subdivision 35 (added by section 2 of Part C, Chapter 58 of the Laws of 2009) permits very limited rate appeals, as noted in PHL 2807-c (35)(b)(x).

Reimbursement for certified home health agencies (CHHA) is set forth in 10 NYCRR 86-1.46. This is not impacted by the new subdivision 35. Consequently, CHHA rate appeals based on new DOH mandated services may continue to be available.

For long-term home health care programs, reimbursement is found in Subpart 86-5 of 10 NYCRR and section 86-5.14(a)(3) and permits the commissioner to consider applications for revision of certified rates which are based on "significant increases in the overall

operating costs of the long term home health care program resulting from the implementation of additional programs, staff or services specifically mandated for the program by the commissioner."

Diagnostic and treatment centers (D&TC) rates were scheduled to move to a new system (APGs) on March 1, 2009, but the transition has not occurred due to a delay in federal approval of state plan amendments. In the interim, 10 NYCRR 86-4.16(c) would continue to permit D&TC rate appeals based on new mandates.

Cost to State and Local Government:

The regulatory requirements are not expected to result in costs to state or local governments. Potential savings to Medicaid and other payors are expected by decreasing influenza cases. Among healthy persons aged 18-64 years, vaccination(s) can save an estimated \$60-\$4,000 per illness, depending on the cost of vaccination(s), the influenza attack rate, and vaccine effectiveness against influenza-like illness (ILI). In another economic analysis, vaccination(s) resulted in an average annual cost savings of \$13.66 per person vaccinated; however, other analyses have not demonstrated cost savings. Among studies of healthy young adults, >70% of the costs prevented were associated with reductions in lost work productivity. The estimated annual direct cost of influenza infection in the United States is estimated to be between 3 and 5 billion dollars.

In the event that medical facilities and long-term home health care programs seek a timely medicaid rate change and it is approved, the state and local government may have to pay a proportion of the amount approved, with the federal government contributing the balance.

However, due to the medicaid cap imposed on the county share, it is impossible at this time to calculate whether local governments will in fact have to contribute any funds to meet this potential expense.

Cost to the Department of Health:

Minimal new costs to the New York State Department of Health (NYSDOH) will be incurred associated with enactment of these regulations. By decreasing HCP influenza disease and absenteeism, and the spread of influenza disease among patients, the quality of health care should be improved, as well as patient outcomes.

NYSDOH has dedicated multiple resources to promote voluntary HCP vaccination(s) programs in public health and private arenas, including hospitals, clinics, and local health organizations over the past decade. As previously mentioned, the standard for care in New York State is that all HCP should receive annual influenza vaccination(s). This recommendation was sent to all New York State hospitals, long-term care facilities, providers and local health departments, via two Commissioner letters (dated October 2006 and September 2007), and a Health Advisory (December 14, 2007). Other initiatives to promote this practice have included educational materials, toolkits, a department-wide workgroup, outreach to healthcare partners, and public service announcements. These initiatives will continue.

Any additional costs will be associated with increased oversight of compliance with the regulatory requirements. NYSDOH already collects data from long-term care facilities on an annual basis to monitor compliance with PHL Article 21-A. Long-term care facilities must submit an annual report (DOH form 4193) to NYSDOH by May 1 providing information on the

number of residents and employees who received and the number who did not receive influenza and pneumococcal vaccine during the previous year. This form will be modified to capture data from additional health care facilities. Additional costs will mostly involve the additional data collection, analysis, written reports and follow-up with facilities.

Local Government Mandates:

There are no local government mandates in New York State related to this proposal, except as they apply to providers operated by local government entities.

Paperwork:

PHL Article 21-A, the New York State Long-Term Care Resident and Employee Immunization Act, requires nursing homes, adult care facilities, enriched housing facilities, and adult day health care programs in New York State to document their vaccination efforts and to submit an annual report to NYSDOH. The facility annual report was historically completed using DOH form 4193. This form is now available on the Health Provider Network (HPN). The form will be modified to capture hospitals, diagnostic and treatment centers, home care and hospice programs. Those entities covered by these regulations will be required to submit vaccination information using the Health Commerce System. All reporting will be accomplished using the internet only.

Duplication:

This proposal does not duplicate any state or federal regulation.

Alternative Approaches:

Voluntary programs to increase HCP influenza vaccination rates have not resulted in adequate vaccination levels. For the past decade, the New York State Department of Health has dedicated multiple resources to promote voluntary HCP vaccination programs in public health and private arenas, including hospitals, clinics, and local health organizations. Initiatives have included educational materials, toolkits, a department-wide workgroup, outreach to healthcare partners, and public service announcements. However, these programs have failed to substantially increase HCP vaccination rates.

On April 1, 2000, Article 21-A, the Long-Term Care Resident and Employee Immunization Act, was added to the Public Health Law. This law requires nursing homes, adult homes, enriched housing programs, and adult day health care programs to provide or arrange for influenza vaccination(s) for all residents and employees every year. The law also requires these types of facilities to provide or arrange for pneumococcal vaccination(s) for all residents and employees for whom the vaccine is recommended according to guidelines issued by the Advisory Committee on Immunization Practices. Residents and employees may refuse vaccination(s) due to medical contraindication, religious objection, or by choice after being fully informed of the health benefits and risks of such action. These long-term care facilities must document vaccination status of residents and employees, including refusal of vaccination(s) and the reasons for refusal.

In 2001, NYSDOH began collecting data from long-term care facilities to monitor compliance with PHL Article 21-A. Long-term care facilities must submit an annual report

(DOH form 4193) to NYSDOH by May 1 providing information on the number of residents and employees who received and the number that did not receive influenza and pneumococcal vaccine during the previous year. Even the enactment of NYS PHL Article 21-A targeting long-term care facilities has failed to promote consistent HCP vaccination rates above 44%.

A requirement for vaccination(s) is not unique to influenza. Childhood vaccination rates vastly improved in the US, often exceeding 90–95%, once mandatory school-entry vaccination requirements were put into place. In health care settings, measles and rubella vaccination has also been successful in achieving nearly universal vaccination of health employees against these pathogens. Consequently, requiring influenza vaccination(s) for health care workers would similarly be highly effective and, perhaps with additional education, widely accepted.

Federal Requirements:

There are no minimum standards established by the federal government for the same or similar subject areas.

Compliance Schedule:

This proposal will go into effect upon filing with the Secretary of State.

Contact Person:

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Bureau of House Counsel, Regulatory Affairs Unit
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Empire State Plaza
Albany, NY 12237
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REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect of Rule:

Any facility defined as a hospital pursuant to PHL Article 28, as a home care services agency by PHL Article 36, or hospice by PHL Article 40 will be required to comply. Small businesses (defined as 100 employees or less), independently owned and operated, affected by this rule will include: 3 hospitals, 237 diagnostic and treatment centers, 91 nursing homes, 252 certified home health agencies, and approximately 900 licensed home care services agencies. There are 50 certified hospices in New York State; most of them would fit into the category of a small business, but definitive data concerning their small business status is not available.

Compliance Requirements:

All facilities must document the preemployment and annual vaccination(s) for influenza virus, subject to the availability of an adequate supply of the necessary vaccine and subject to exemptions for medical contraindications.

Professional Services:

Facilities will need to provide or arrange for influenza vaccination(s) of personnel. Most facilities currently offer influenza vaccinations to their personnel on a voluntary basis. It is not anticipated that facilities will need to hire additional staff to meet this mandate.

Compliance Costs:

The cost to facilities to meet this mandate is estimated to be minimal. It is anticipated that any costs incurred to vaccinate HCP will be offset by savings in direct medical costs by reducing influenza infection among HCP and patients, as well as savings in indirect costs associated with HCP absenteeism.

Economic and Technological Feasibility:

This proposal is economically and technically feasible.

Minimizing Adverse Impact:

There are no alternatives to the proposal to require influenza vaccination(s) of all HCP.

Small Business and Local Government Participation:

Outreach to the affected parties has been conducted. Such parties include professional organizations representing physicians, nurses, and other health care personnel, as well as general hospitals, diagnostic and treatment centers, home care agencies and hospices.

The organization representing county health officers, NYSACHO, has also been briefed. Organizations that represent the affected parties are given notice of this proposal by its inclusion on the agenda of the Codes and Regulations Committee of the State Hospital Review and Planning Council (SHRPC).

Presentations by Department staff were also given at the full Public Health Council and State Hospital Review and Planning Council meetings to brief Council members on this

upcoming proposal. The public, including many affected parties, have been in attendance at these meetings.

RURAL AREA FLEXIBILITY ANALYSIS

Pursuant to section 202-bb of the State Administrative Procedure Act (SAPA), a rural area flexibility analysis is not required. These provisions apply uniformly throughout New York State, including all rural areas.

The proposed rule will not impose an adverse economic impact on rural facilities defined within PHL Articles 28, 36, or 40. It will require additional documentation, record-keeping and other compliance requirements on public or private entities, but it is not expected to adversely affect rural areas.

JOB IMPACT STATEMENT

A Job Impact Statement is not included in accordance with Section 201-a (2) of the State Administrative Procedure Act (SAPA), because it will not have a substantial adverse effect on jobs and employment opportunities.

EMERGENCY ADOPTION JUSTIFICATION

Transmission of influenza disease from health care personnel to patients is a serious and significant patient safety issue because influenza disease is a leading cause of morbidity and mortality among hospitalized patients and those admitted to other types of health care facilities. This fact, plus the new threat posed to health and safety by the novel H1N1 influenza A strain that is circulating in New York State, puts a need for emergency regulations requiring that all health care personnel (HCP) be immunized against influenza annually into focus for the upcoming influenza season. Yearly, a significant threat to the health of patients, HCP themselves, and local communities exists that will be magnified in the upcoming season by the ongoing pandemic. The sooner that the emergency regulations are in place the sooner lives will be saved and other complications of influenza disease avoided.

Each year, influenza causes significant morbidity and mortality in the United States, especially among the vulnerable populations in hospitals and other health care facilities. Complications of influenza may include bacterial or viral pneumonia; dehydration; the worsening of chronic medical conditions, such as congestive heart failure, asthma, or diabetes; or death. The risk for complications, hospitalization, and death from influenza are higher among persons 65 years of age or older, young children, and persons with chronic medical conditions. Influenza is the sixth leading cause of death among adults in the United States, killing an average of 36,000 Americans annually and causing more deaths than all other vaccine-preventable diseases combined.

Recognizing the need to protect patients, the Centers for Disease Control and Prevention (CDC) has recommended influenza vaccination for HCP since 1981. In February 2006, the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory

Committee on Immunization Practices (ACIP) jointly recommended that all HCP be vaccinated annually against influenza. In addition, the Infectious Disease Society of America, the Society of Hospital Epidemiologist of America, the American Medical Association, the American Academy of Family Practitioners, the American Academy of Pediatrics, the Association of Perioperative Nurses, the American Nurses Association, and multiple individual health care institutions have all supported and called for all HCP to receive influenza immunization yearly. Facilities that employ HCP have been strongly encouraged to provide vaccine to their staff by using evidence-based approaches that maximize the use of influenza vaccination.

Yet, despite the documented and positive effects of immunizing HCP against influenza on patient outcomes, HCP absenteeism, and reducing influenza infection among staff, and the fact that influenza transmission and outbreaks in healthcare facilities are well documented, national vaccination coverage rates among HCP continue to remain low, at around 42%. Even among health care centers utilizing highly organized and aggressive campaigns and incentives to promote immunization of HCP, 30–50% continue to remain unvaccinated. In 2000, New York State enacted Public Health Law Article 21A requiring long term care facilities to offer influenza vaccine to all residents and HCP and to document refusal of the vaccine. As seen in New York State Department of Health (NYSDOH) survey data, while the overall vaccination of residents has improved to 80% or greater in most facilities, the response among HCP has been poor.

Because of the serious consequences of nosocomial influenza outbreaks, as well as the impact on health care workers and the economic impact on health care systems, it is imperative that action be taken to ensure high health care worker vaccination rates. HCP absenteeism can result in serious staffing shortages during the influenza season, at a time when emergency room visits and admissions due to influenza-related illness are greatly increased. The benefit of an immunized staff decreases direct and indirect costs to health care facilities. The United States

and New York State are entering the 2009-2010 influenza season this Fall facing an emergency situation, with the potential circulation of both seasonal influenza viruses and the pandemic novel H1N1 influenza strain. Health care resources will be strained to the breaking point while addressing the burden of treating large numbers of patients ill with influenza. HCP need to be protected so that they will not become ill, transmit influenza to patients, their families and their communities, and also so that the health care system can be preserved and not collapse due to high degrees of HCP absenteeism. The urgency of this situation necessitates immediate emergency regulatory action to allow sufficient time for hospitals to arrange for the purchase and administration of influenza vaccine for the upcoming influenza season. This will also give health care facilities time to prepare for an extended novel H1N1 influenza vaccination campaign, in tandem with seasonal vaccination efforts.

Immunizing the staff of health care facilities against influenza will promote the health and safety of the patients they serve and support efficient provision of services during the pandemic. The NYSDOH has strongly and continuously advocated that all HCP should receive annual influenza vaccination(s). Annual influenza morbidity and mortality necessitates requiring influenza vaccination of all HCP in hospitals and other health care facilities on an emergency basis, so that lives can be saved. This is an even more urgent imperative during the current novel H1N1 influenza pandemic.

Summary of Key Points

- The burden of influenza disease is very high in health care facilities and will increase due to the current pandemic.

- Influenza vaccination of HCP is a patient and community safety issue and protects vulnerable hospitalized patients during seasonal influenza seasons and during the pandemic.
- HCP need to be vaccinated to control influenza in health care facilities even if patient vaccination rates are high.
- During the pandemic, it may be recommended that HCP receive influenza vaccination as the first line of protection of the public.
- Seasonal and pandemic influenza vaccination can be cost saving to health care facilities by decreasing absenteeism, improving patient outcomes, decreasing error rates, increasing quality of care, and decreasing personal and organizational expenditures.
- Voluntary programs to increase HCP influenza immunization rates have not resulted in adequate immunization levels.



STATE OF NEW YORK DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Richard F. Daines, M.D.
Commissioner

James W. Clyne, Jr.
Executive Deputy Commissioner

August 26, 2009

**RE: Health Care Worker Mandatory
Influenza Immunization**

Dear Administrator:

On August 13, 2009 an emergency regulation went into effect, which requires that all personnel of certain health care settings receive annual vaccinations against influenza by November 30 of each year unless they have a medical contraindication to the vaccination or the State Commissioner of Health determines that there is an insufficient supply of vaccine for the year. The primary purpose of this regulation is to protect the health and safety of vulnerable patients, whose risk of serious adverse effects from influenza is high. An added benefit is to maintain a healthy workforce during flu season.

The new regulation applies to:

- Hospitals
- Diagnostic and treatment centers licensed under Article 28,
- Home care services agencies licensed under Article 36 of the Public Health Law including:
 - ◆ Certified home health agencies
 - ◆ Licensed home care services agencies
 - ◆ Long-term home health programs including AIDS home care programs
- Hospice programs certified under Article 40 of the Public Health Law.

Personnel who must be vaccinated against influenza include all those affiliated with the employer, paid or unpaid, who have direct contact with patients or whose activities are such that they pose a risk of transmission of influenza to patients or to those who provide direct care to patients. "Personnel" is defined as anyone affiliated with any organization (noted above), including but not limited to employees; members of the medical staff, including attending physicians; contract staff; students and volunteers.

The organization is responsible for determining which individual members of the employer's personnel pool fall into the group requiring vaccination consistent with the regulation. Additionally, the organization is responsible for identifying the measures that are needed to protect patients from influenza transmission from personnel who are exempt due to a medical contraindication. The organization covered by these regulations which provides the vaccination must provide it at no cost to

RE: Health Care Worker Mandatory Influenza Immunization

their personnel. However, personnel are free to receive their vaccinations wherever they please as long as they provide documentation to the organization. The organization should confer with their Human Resources office and counsel to determine what actions to take for personnel who fail to meet the mandatory requirement; we suggest that organizations examine their existing policies for mandatory rubella, rubeola, measles, and TB testing for guidance.

Nursing homes, adult homes, enriched housing programs, adult day health care programs and any other facility providing residential housing and supportive services to 5 or more persons over the age of 65 who are unrelated to the operator continue to be governed by the requirements of Article 21-A of the Public Health Law, which remains unchanged from last year.


If the novel H1N1 vaccine is released as a fully licensed vaccine, as expected, this regulation will also require immunization against H1N1 as well as seasonal influenza this coming season. Further information will be provided when the Department receives updates on the vaccine, its licensure status and availability this fall.

The regulation and current version of the Question & Answer document are attached in anticipation of any further questions you may have. Please check the Health Provider Network (HPN) for updates.

Sincerely,



Mark Kissinger
Deputy Commissioner
Office of Long Term Care



Richard M. Cook
Deputy Commissioner
Office of Health Systems Management

Attachments

MANDATORY SEASONAL AND H1N1 FLU VACCINATION: Q & A

As reported in previous communications, New York State recently passed emergency regulations making it **mandatory** for all healthcare workers and volunteers who have direct patient contact -- or whose activities are such that if they were infected with influenza could potentially spread it to healthcare workers or patients - to be vaccinated this year against both seasonal influenza and the H1N1 ("Swine Flu") virus.

The Q&A below has been developed to address some important questions that members of the Downstate community might have, and to provide updated information on how we plan to move forward to ensure full compliance with these new regulations.

Q: *Is vaccination against seasonal influenza and the H1N1 virus really mandatory for healthcare workers who have direct and indirect contact with patients?*

A: Absolutely. It is no longer voluntary -- **it is an enforceable emergency public health regulation**. If you are not vaccinated, you will not be allowed to work or practice in a patient care environment. Failure to comply will result in penalty measures being pursued, up to and including termination from Downstate Medical Center employment.

Vaccination not only protects yourself, it also protects our patients. We need all staff affected by the emergency regulations to comply.

Q. *Will anyone be exempt from the mandatory vaccinations?*

A. Yes. Individuals with documented medical contraindications to flu vaccine will be excused.

Q. *Will Downstate provide vaccinations for its healthcare workers and volunteers?*

A. Yes. Vaccinations will be provided free of charge against both seasonal influenza and the H1N1 virus. You may also choose to receive vaccinations from your private physician or another provider; if you do so, you will be required to present documentation that you have been properly vaccinated.

Q. *How will I know if I am required to receive the mandatory vaccinations against seasonal influenza and the H1N1 virus?*

A. If you have direct contact with patients or perform duties that, if ill could infect patients or staff with direct patient contact, you will need to be vaccinated. It includes clerical, dietary, housekeeping, and maintenance workers who work in patient care areas.

Staff who only have incidental contact with direct care workers in the course of their work are not required to be vaccinated -- e.g. passing through nonpatient unit hospital hallways, using public rest rooms, or riding in nonpatient transport hospital elevators.

All students in Medicine, Nursing, and Health Related Professions need to be vaccinated. Students in the Schools of Graduate Studies and Public Health need to be vaccinated if they have patient care exposure, or work with individuals who have patient care exposure.

"Direct contact" refers to persons who, if they were infected with influenza, could transmit the disease to a patient. Large-particle respiratory droplets that do not remain suspended in the air primarily transmit influenza. Therefore, direct contact would be either through sharing a 6-foot space with a patient (person-to-person contact) or a surface that comes in contact with a patient (equipment-to-patient contact).

Hospital and Center Administration will be working closely with individual departments, the colleges, Employee-Student Health, Human Resources, and IT Services to identify all employees who need to be

vaccinated. All non-salaried, voluntary physicians, and volunteers who see or interact with patients must be vaccinated as well.

Q. If I get vaccinated, do I need to follow other precautions?

A. Even with H1N1 and seasonal flu vaccination, you can still spread influenza-like-illness (ILI) to others as it takes at least 2 week after the vaccine has been administered for protective antibodies to sufficiently develop.

All employees and visitors should take everyday actions to stay healthy and prevent transmission of influenza like illnesses (ILI):

- Cover your nose and mouth with a tissue when you cough or sneeze. Throw the tissue in the trash after you use it.
- Wash your hands often with soap and water, especially after you cough or sneeze. Alcohol-based hand cleaners are also effective.
- Avoid touching your eyes, nose, or mouth. Germs spread that way.
- Stay home if you get sick. The CDC recommends you stay home from work or school and limit contact with others to keep from infecting them.

Q. I work in an office in the hospital but don't take care of patients. Do I need to get vaccinated?

A. Yes. All individuals who work in University Hospital of Brooklyn need to be vaccinated.

Q. I work in FM&D. Do I need to get vaccinated?

A. If your work takes you in the hospital and you have direct contact with staff that have direct contact with patients, you need to be vaccinated.

Q. I work in the HSEB and my friend works in the BSB building. Do we need to get vaccinated?

A. If your work regularly takes you over to the hospital, and you have direct contact with staff that has direct contact with patients, you need to be vaccinated.

Q. What motivated the New York State Legislature to pass these new regulations?

A. Mandatory vaccination was deemed necessary in anticipation of a potentially serious upcoming fall flu season. Further spread of the H1N1 virus, coupled with normal seasonal influenza, could result in unprecedented challenges, particularly for New York City's hospitals and emergency rooms.

Q. When will vaccinations be available?

A. Seasonal flu vaccines are available now and you can get them in Employee-Student Health Services. We are expecting our stock of H1N1 vaccine to arrive shortly, and we will be sending out information on dates and places to be vaccinated. We plan to use the Point of Distribution (POD) concept in Sodhexo Court in addition to strategically placed vaccination stations throughout the hospital.

Q. What will be the final day to receive vaccinations?

A. Under the emergency public health regulations signed by the Governor, all affected healthcare workers, employees, and volunteers must be vaccinated for both seasonal and H1N1 flu by **November 30**.

Q. How many vaccinations will I need to receive?

A. Protection against seasonal influenza, just as in years past, is a single vaccination. For adults, H1N1 vaccination also requires a single shot. You can take the shots together in separate arms or separately.

Q. What if I get vaccinated at another hospital or by my private practitioner?

A. You will need to provide proof of vaccination – minimum a signed vaccination card or a statement from the provider of the vaccine giving the date the vaccine was given, type of vaccine (Name), lot #, and the name and address of the provider.

The information can be faxed to the Student-Employee Health Service at 718-270-2477 (a secure fax), mailed to Box 33, or hand-delivered to 440 Lenox Road, Apartment 1-S. Keep a copy for your records.

This information is generally available on the flu consent form. The consent form will be maintained in your Student/Employee Health record. You can request a copy of the consent form at the time of vaccination.

Q. *Have patients had any side effects from the H1N1 vaccine during clinical trials?*

A. Reports from the H1N1 clinical trials indicate that there have been no serious adverse side effects. Adverse effects reported by participants have been similar to those we see each year during vaccination against seasonal flu – soreness at the inoculation site, mild headache and an occasional case of malaise.

Q. *How will my supervisor and others know that I have been vaccinated?*

A. Strict records will be kept on employees receiving vaccinations and those who still need to be vaccinated. This information will be shared with supervisors. It must also be shared with the State Department of Health to ensure our compliance with State regulations.

Q. *What if I have questions?*

A. If you have questions or concerns, please speak directly with your supervisor. He or she will help you find the appropriate answer. The staffs in your hospital's Departments of Infection Control and Employee-Student Health Services also are valuable resources for information.

If you are looking for general information about seasonal influenza and/or H1N1 influenza, you can visit the H1N1 information site through the link on the home page, which provides additional links to the web sites for the CDC and the State and City Departments of Health web sites. They have information on influenza that is continually updated.



EASTERN NIAGARA HOSPITAL

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2600 William Street
Newfane, New York 14108
(716) 778-5111

Lockport Site
521 East Avenue
Lockport, New York 14094
(716) 514-5700

To: All Employees

From: David J. Steinwald, Director of Human Resources
Lynne L. Blanchard, Assistant Administrator for QA & RM

Date: October 8, 2009

As you may know, all hospitals were notified by the NYSDOH in August 2009 that an emergency regulation went into effect which requires that all personnel (with specified exceptions) receive annual vaccinations against influenza unless they have a medical contraindication to the vaccination or the NYS Commissioner of Health determines that there is an insufficient supply of vaccine for the year. Please note that the H1N1 (swine flu) vaccine is has now also been mandated by NYS. Therefore, the following information also applies.

This must be done by November 30th of each year. NYS is requiring the Hospital to ensure that these immunizations occur and will be monitoring it. Salient aspects of the process follow below:

Scope:

The NYS requirement applies to all employees who either

- provide direct patient care (including but not limited to RNs, LPNs, aides, x-ray techs, phlebotomists, physical therapists, respiratory therapists, counselors, OR techs, clinic staff, EKG techs, med techs) or
- have direct contact with patients (including but not limited to housekeepers, maintenance workers, dietary workers, registration staff, UR and discharge planning staff) or
- whose activities are such that they could potentially expose patients (including but not limited to pharmacists and pharmacy techs, central supply staff, medical record clerks).

Please understand that, since NYS has mandated the vaccine for health care workers, you are required to have the vaccination(s) in order to hold your position.

While there are some other job titles for which the vaccination does not seem to be mandatory, these instances are limited. The Director of Human Resources is responsible for administering these requirements. Any questions on job titles not listed above should be directed to Dave Steinwald.

Contraindications:

Medical contraindications recognized by the Advisory Committee on Immunization Practices (ACIP) will be recognized by NYS. Only physicians, licensed physician's assistants and nurse practitioners can authorize a medical exception and must so attest to it in writing.

All employees, whose jobs would otherwise require them to be vaccinated, who present documentation of a medical contraindication must meet with Laurie Haight for education on proper infection control techniques. Depending on how many exempted employees, Ms Haight will determine whether to conduct these sessions either one-on-one or in groups.

Obtaining the Vaccination

The Hospital will offer the vaccine to all employees (as well as physicians and volunteers) free of charge. The Hospital will maintain the required documentation.

Should you prefer, you may obtain the vaccination elsewhere (eg: another hospital, your own physician). In that case, you will be required to provide to this Hospital proof of vaccination with the specific documentation that NYS requires. That documentation is as follows:

- date
- site of administration
- type of vaccine
- dose
- manufacturer
- lot number of the vaccine
- reactions, if any
- vaccine information statement given
- the name of the person administering the vaccines

Immunization times and locations are posted in the Hospital. You may obtain the vaccine during any of these times. You may be vaccinated during your workday. Department heads and supervisors will work with you to facilitate logistics. Should you wish to be vaccinated at your convenience during non work time (eg before or after your shift or on a day off), you may do so.

Laurie Haight (or Lynne Blanchard) is available to assist you with questions related to either the vaccine or the required documentation if you wish to obtain the vaccination elsewhere.

Lori Ballengee, MS
Public Health Director
E-mail: ballenl@alleganyco.com

**ALLEGANY COUNTY
DEPARTMENT OF HEALTH**
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585-268-9250
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Thomas E. Hull, MS
Deputy Public Health Director
Director of Environmental Health
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MEMO

TO: All Health Department Employees, John Margeson, Tom Miner, Ellen Ruckle, AFSCME, NYSNA
FROM: Lori Ballengee, Public Health Director
RE: Mandatory Vaccinations under Public Health Law
DATE: October 5, 2009

As you all know, there have been many meetings and much debate over the new law that requires all staff contained within a hospital, home care and Diagnostic and Treatment Center environment, to receive the seasonal and H1N1 vaccinations, along with the MMR and annual TB test. After a meeting last week, the determination was made that Allegany County must and will adhere to the law.

For those with a genuine fear or phobia of needles, we suggest you utilize the Employee Assistance Program and perhaps they can help you through the process. There are several of their brochures hanging throughout the department.

Please remember, this is a New York State, not county, law. If it helps, remember, you can be contagious one to two days before you present with symptoms and up to five days after. You do not want to risk getting infected, not know it, and take it home to your families, your grandchildren, elderly parents or your friends. For those who already get a seasonal flu shot, the H1N1 is also licensed by the FDA, as is seasonal, and we are told there has been more research and clinical trials done with H1N1 than ever happens with seasonal flu. Please remember to also use good hygiene techniques to help prevent the spread of many diseases.

For those that refuse to receive the required vaccinations and/or TB testing, I will have no choice but to institute the disciplinary process for insubordination. It is considered a condition of employment to comply with all state laws and refusal would deem you unfit for duty.

I was hopeful we would be able to find a way around this, but it is the law and we have to adhere to it. Please let Janet know your intentions as far as complying with the mandated requirements. We need to have all of these documented in your Employee Health Record for when the state audits us. We are also told we will have to report to the state in the spring how many of our staff were vaccinated. When the next round of seasonal flu vaccine comes in, and the first round of H1N1, Health Department staff will be first to receive them. Thank you for your cooperation with a very difficult matter.

Balas, Lisa

From: Barbara Zittel [BZITTEL@MAIL.NYSED.GOV]
Sent: Friday, September 04, 2009 16:06
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Subject: Friday's Update

I think that you all are aware of the regulation that was passed by the Department of Health mandating that all health workers in acute care hospitals be required to receive an annual seasonal flu vaccine. For those of you in hospitals, staff must be frantically trying to meet that mandate.

In the last week we have received a number of calls from nurses who are considering refusing the vaccine. When we inform them that they may lose their positions, they respond with "I don't care. I'll find another job. My question is can I lose my license over my refusal?"

Of course, no nurse will have a license revoked or even suspended...BUT, there may be negative repercussions from such a refusal. In speaking with Jim Hines, Esq., one of our Administrative Officers (AO), he provided the following advice:

Failure of a nurse to comply with the new DOH regulation mandating immunization could be considered professional misconduct, based upon 29.1(b)(1), which reads as follows:

Unprofessional conduct in the practice of any profession licensed, certified or registered pursuant to title VIII of the Education Law, except for cases involving those professions licensed, certified or registered pursuant to the provisions of Article 131 or 131-B of such law in which a statement of charges of professional misconduct was not served on or before July 26, 1991, the effective date of Chapter 606 of the Laws of 1991, shall include:

willful or grossly negligent failure to comply with substantial provisions of Federal, State or local laws, rules or regulations governing the practice of the profession;

Just thought you'd like to know this.

Enjoy your weekend!

Barbara

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